

Daniel M. Silver
Partner
405 N. King Street, 8th Floor
Wilmington, DE 19801
T. 302-984-6331
F. 302-691-1260
dsilver@mccarter.com



October 9, 2018

PUBLIC VERSION FILED: October 30, 2018

VIA CM/ECF & HAND DELIVERY

The Honorable Colm F. Connolly
844 N. King Street
Wilmington, DE 19801-3555

Re: **Genentech, Inc. v. Amgen Inc., C.A. Nos. 17-1407-CFC, 17-1471-CFC (D. Del.)**

Dear Judge Connolly:

Plaintiffs respectfully respond to Defendant Amgen's letter of October 5, 2018.

1. The Scheduling Order sets two deadlines relevant to this dispute: (1) August 31, 2018, for Plaintiffs to "reduce the number of patents" from the twenty-six asserted to "no more than eight;" and (2) September 17, 2018, for Plaintiffs to "identify no more than twenty claims for claim construction and trial." D.I. 106 ¶ 2. During the Rule 16 proceedings, the Court overruled Plaintiffs' constitutional objection to the compelled reduction of patents and claims, *see In re Katz Interactive Call Processing Pat. Litig.*, 639 F.3d 1303, 1312-13 (Fed. Cir. 2011), but made clear that the deadlines were subject to Plaintiffs obtaining adequate discovery to inform the selections.¹ Judge Sleet emphasized the point again in August, in overruling Amgen's objections to Plaintiffs' discovery:

Genentech's Counsel: What I did mean to say is that we did not want to reduce the patents to eight on the schedule that we were given, but we are going to do that. It was certainly the case and I think we were all clear that we were entitled to adequate discovery to make an intelligent decision of which ones to drop.

The Court: *No doubt about that.* That is not something of which you have to convince me. *That makes sense I hope to everyone on the line.*

¹ See Ex. A (May 7, 2018 Tr.) at 51-52 ("I am rather persuaded by your point, your points regarding the plaintiff needing to make a selection. But I am also persuaded by [Genentech's counsel's] point about this is part of a process whether we are going to assert rights that our client owns and has a right to vindicate because your client has alleged infringing activities and not wanting to inappropriately prematurely, as was the argument in *Katz*, and I am sure is the argument in those cases you looked at, cut off an opportunity . . .").

The Honorable Colm F. Connolly
 October 9, 2018
 Page 2

Ex. B (July 26, 2018 Tr.) at 10 (emphasis added).

On August 31, relying on the contentions Amgen provided during the BPCIA's mandated pre-litigation information exchanges and the discovery adduced to that date, Plaintiffs identified eight of the twenty-six asserted patents (while preserving their due process objection). On September 17, again noting their objection, Plaintiffs identified eighteen claims from six of those patents. As to the other two, U.S. Pat. 8,512,983 ("Gawlitzeck") and U.S. Pat. 9,441,035 ("Carvalho"), Plaintiffs slashed the number of asserted claims from fifty to nineteen but objected to further reductions at that time because Amgen had produced insufficient discovery to permit an informed selection.

As shown in the attached appendix, the claims listed from Carvalho and Gawlitzeck require specific concentrations of particular chemicals—cystine, or asparagine and glutamine—during the antibody manufacturing process. Plaintiffs sought this information from Amgen by way of Rule 30(b)(6), but Amgen's witness could not provide it, [REDACTED]

Ex. C (Nack Tr.) at 192:4-15

196:4-13

[REDACTED]; 242:18-23 [REDACTED] Plaintiffs have sought to discover these facts by requesting samples from Amgen's manufacturing process repeatedly over the last eighteen months, but Amgen has refused to cooperate. Worse, during the 30(b)(6) deposition, Amgen's witness acknowledged [REDACTED]

[REDACTED] See Ex. C at 203:10-204:2.

On the present record, reducing the number of claims from the Gawlitzeck and Carvalho patents requires Plaintiffs to shoot in the dark, violating their due process rights. *See Katz*, 639 F.3d at 1313 & n.9 ("[A] claim selection order could come too early in the discovery process, denying the plaintiff the opportunity to determine whether particular claims might raise separate issues of infringement[.]"). Although Amgen avers that the parties made "reasonable efforts" to resolve this disagreement, Amgen in fact refused to confer about (i) this issue, (ii) Amgen's discovery failures and spoliation of evidence, and (iii) ways in which to work through the issue without affecting the schedule. In the meantime, there should be no prejudice to Amgen by deferring a final claim selection for Gawlitzeck and Carvalho. The parties have not yet begun the *Markman* process, and the temporary inclusion of additional claims that are unlikely to introduce new claim construction disputes should not increase the burden on the Court or affect the schedule.

2. The Scheduling Order—the subject of extensive negotiation between the parties and two full days of hearings before Judge Sleet—sets January 11, 2019 as the deadline for substantial completion of *all* document production. There is no basis for Amgen's request to, in effect, amend the Order to add an interim deadline for substantial completion of non-custodial documents. Amgen's suggestion that Plaintiffs have delayed is wrong—to date, Plaintiffs have produced more than 750,000 pages of documents. And Amgen's purported need for these documents is baseless. Under *Phillips*, they are minimally relevant (if that) to claim

The Honorable Colm F. Connolly
 October 9, 2018
 Page 3

construction. Were it otherwise, Amgen never would have pressed for claim construction proceedings to occur well before the production deadline in the Scheduling Order.

3. Plaintiffs are seeking damages for infringing manufacturing by Amgen beginning in 2017. Despite this, Amgen insists Genentech must produce documents dating all the way back to 2009, on the theory that such an early date is necessary to capture Genentech's earlier planning for biosimilar competition, as well as to assess any change in that planning over time. But Amgen has not explained how changes in Genentech's views over time could be relevant either to damages or Genentech's entitlement to injunctive relief. Moreover, based on Genentech's investigation, the relevant modelling and planning for biosimilar entrants into the bevacizumab market did not begin until late 2015. Genentech agrees that if either side discovers documents memorializing a model, forecast, and plan for biosimilar entrants that predate 2015, those documents should be produced.² But Amgen's blanket request that Genentech search the files of its identified damages custodians dating back to eight years before the alleged infringement is not reasonably proportional to the needs of these cases given the irrelevance of those earlier documents.

4. The negotiated ESI order requires the parties to select eight custodians with "discoverable information" from among their own employees. Genentech also agreed to produce the files of the named inventors of the remaining asserted patents. Amgen complains that Genentech should have chosen different custodians with more information on "technical issues." But Amgen never explains what relevant, non-cumulative information it expects such custodians to possess beyond the information Genentech has produced from the inventors and non-custodial records. For example, while Amgen requests "custodial discovery on Genentech's manufacture of Avastin," it ignores that Genentech already has produced the Avastin BLA, the extensive regulatory filing describing Genentech's process for making Avastin. In any event, Amgen's assertion that that Genentech has refused to provide discovery about "technical" issues is specious, given that the inventors' custodial files are being produced.

5. Apparently fishing for defenses it has not identified, Amgen asks the Court to order the production of materials generated and served by Plaintiffs' opponents in other litigation. This discovery is burdensome and unnecessary. As Plaintiffs have explained in their pending motion, *see* D.I. 128 (-1407)/D.I. 126 (-1471), Amgen is not entitled to expand the contentions it already served under the BPCIA. Regardless, the discovery sought is cumulative. For twenty IPR proceedings involving the patents-in-suit, Plaintiffs are producing the entire record. Similarly, for seventeen district court cases, Plaintiffs have agreed to a production that includes at least some pleadings and expert reports served by opposing parties (but excludes, for example, opposing parties' expert reports regarding infringement and damages). Any meaningful (in)validity contention in any of these cases would be revealed in the responsive reports from Plaintiffs' experts in those cases, which will be included in the agreed-upon production.

² As Amgen notes, Genentech has also offered to collect sales and profit and loss data for Avastin going back further than 2015 in response to Amgen's request for information about the demand for Avastin prior to 2015.

The Honorable Colm F. Connolly
October 9, 2018
Page 4

Respectfully submitted,

/s/ Daniel M. Silver

Daniel M. Silver (#4758)

cc: Counsel of Record (via electronic mail)

APPENDIX OF CLAIMS

Genentech's letter of September 17, 2018 identified the following claims. The emphasized limitations are affected by the discovery issues discussed in the attached letter. Bracketed claims are claims that were not identified, but are incorporated into dependent claims that were identified.

A. Carvalho

[1. A method of producing bevacizumab, or a fragment thereof, comprising the step of culturing a Chinese hamster ovary (CHO) cell comprising a nucleic acid encoding bevacizumab or fragment thereof in a cell culture medium, wherein the cell culture medium comprises copper, insulin, and cystine, **wherein the cystine is at a concentration of from 1.25 mM to 2.5 mM**, and wherein the cell produces bevacizumab, or a fragment thereof.]

2. The method of claim 1, wherein the cell culture medium further comprises a plant peptone, a porcine peptone, or both a plant peptone and a porcine peptone.

14. The method of claim 1, wherein the cell culture medium comprises **cystine at a concentration of about 1.3 mM**.

33. The method of claim 1, wherein the method further comprises the step of adding cysteine to the cell culture medium.

34. The method of claim 33, wherein **cysteine is added in an amount to provide from about 0.5 to about 2.0 mM cysteine in the cell culture medium**.

35. The method of claim 33, wherein **cysteine is added in an amount to provide about 0.8 mM cysteine in the cell culture medium**.

[41. A method of culturing a Chinese hamster ovary (CHO) cell comprising a nucleic acid encoding bevacizumab, or a fragment thereof, the method comprising the step of contacting the CHO cell with a cell culture medium comprising copper, insulin and cystine, **wherein the cystine is at a concentration of from 1.25 mM to 2.5 mM**.]

42. The method of claim 41, wherein the cell culture medium further comprises a plant peptone, a porcine peptone, or both a plant peptone and a porcine peptone.

54. The method of claim 41, wherein the cell culture medium comprises **cystine at a concentration of about 1.3 mM**.

73. The method of claim 41, wherein the method further comprises the step of adding cysteine to the cell culture medium.

74. The method of claim 73, wherein **cysteine is added in an amount to provide from about 0.5 to about 2.0 mM cysteine in the cell culture medium**.

75. The method of claim 73, wherein **cysteine is added in an amount to provide about 0.8 mM cysteine in the cell culture medium.**

B. Gawlitzek

A process for producing a polypeptide in a mammalian host cell expressing said polypeptide, comprising culturing the mammalian host cell in a production phase of the culture in a **glutamine-free production culture medium** containing asparagine, **wherein the asparagine is added at a concentration in the range of 7.5 mM to 15 mM.**]

2. The process of claim 1 **wherein the asparagine is added at a concentration in the range of 7.5 mM to 10 mM.**

[3. The process of claim 1 wherein said recombinant host cell is an eukaryotic host cell.]

[4. The process of claim 3 wherein said eukaryotic host cell is a Chinese Hamster Ovary (CHO) cell.]

5. The process of claim 4 wherein the mammalian host cell is a dhfr-CHO cell.

6. The process of claim 1 wherein the production medium is serum-free.

[7. The process of claim 1 wherein the production culture medium comprises one or more ingredients selected from the group consisting of 1) an energy source; 2) essential amino acids; 3) vitamins; 4) free fatty acids; and 5) trace elements.]

8. The process of claim 7 wherein the production culture medium additionally comprises one or more ingredients selected from the group consisting of: 1) hormones and other growth factors; 2) salts and buffers; and 3) nucleosides.

9. The process of claim 1 wherein the production phase is a batch or fed batch culture phase.

10. The process of claim 1 further comprising the step of isolating said polypeptide.

11. The process of claim 10 further comprising determining one or more of cell viability, culture longevity, specific productivity and final recombinant protein titer following isolation.

[14. The process of claim 1 wherein the polypeptide is selected from the group consisting of antibodies, antibody fragments, and immunoadhesins.]

[17. The process of claim 14 wherein said antibody or antibody fragment is a therapeutic antibody or a biologically functional fragment thereof.]

19. The process of claim 17 wherein said therapeutic antibody is an antibody binding to a HER receptor, VEGF, IgE, CD20, CD11a, CD40, BR3 or DR5.

Exhibit A

1

3

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

GENENTECH, INC.,) Civil Action

Plaintiff,

v.

AMGEN INC.,) Nos. 17-1407-GMS,
) 17-1471-GMS, and
) 17-1472-GMS
Defendant.)

- - -

Wilmington, Delaware
Monday, May 7, 201810:00 a.m.
Conference

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Senior Judge,
U.S. District Court,
District of Delaware

- - -

APPEARANCES:

DANIEL M. SILVER, ESQ.

McCarter & English, LLP

-and-

DAVID BERL, ESQ.,

PAUL B. GAFFNEY, ESQ.,

TEAGAN J. GREGORY, ESQ., and

LUKE MCCLOUD, ESQ.

Williams & Connolly LLP

(Washington, DC)

Counsel for Plaintiff

10:03:01 1 THE COURT: Good morning.

10:03:02 2 Counsel, you have noticed a change entirely the

10:03:06 3 last session to this. There is a reason for it. It seems

10:03:13 4 to me that a reminder was in order to both parties, but most

10:03:18 5 especially to plaintiff, its counsel, regarding the

10:03:22 6 authority of the Court. The robe is a simple symbol of the

10:03:28 7 Court's authority. Hence, I have it on today, and I am not

10:03:32 8 down there on the Bench in shirt and tie.

10:03:35 9 What occasioned my conclusion that it would be

10:03:41 10 appropriate today to wear this symbol of authority was the

10:03:44 11 tone, tenor, and some of the substance of some of the

10:03:47 12 plaintiff's discussion in its most recent submission to the

10:03:53 13 Court.

10:03:53 14 I think you know what I am talking about, Mr.

10:03:57 15 Berl. I am going to direct my comments mostly to you as

10:04:00 16 lead counsel, and you, Mr. Gutman, as lead counsel.

10:04:05 17 The so-called Katz issue, I doom "so-called"

10:04:14 18 because I don't see it as an issue, we think quite frankly

10:04:17 19 it was rather ill-advised to present it in the manner in

10:04:21 20 which it was presented, not the way I as a lead on a case of

10:04:24 21 any type would want to try to influence and make a judge

10:04:33 22 come around to my point of view by attempting to cudgel him

10:04:37 23 or her about the head about with a constitutional, an

10:04:43 24 alleged constitutional argument that's not really not

10:04:46 25 fleshed out in the papers.

2

4

APPEARANCES CONTINUED:

JAMES HIGGINS, ESQ.

Young Conaway Stargatt & Taylor, LLP

-and-

SIEGMUND Y. GUTMAN, ESQ., and

CATRINA WANG, ESQ.

Proskauer LLP

(Los Angeles, CA)

Counsel for Defendant

- - -

10:02:12 9 THE COURT: Good morning. Please, take your

10:02:14 10 seats.

10:02:14 11 Counsel, let's start out with a round of

10:02:18 12 introductions, beginning with plaintiff, please

10:02:20 13 MR. SILVER: Good morning, Your Honor. Dan

10:02:23 14 Silver on behalf of the plaintiffs. I am joined by my

10:02:27 15 colleagues from Williams & Connolly, David Berl, Paul

10:02:29 16 Gaffney, Teagan Gregory, and Luke McCloud, Your Honor, who

10:02:35 17 represent plaintiff Genentech.

10:02:37 18 Thank you, Your Honor.

10:02:38 19 THE COURT: Good morning.

20 MR. HIGGINS: Good morning, Your Honor. Jim

10:02:45 21 Higgins from Young Conaway Stargatt & Taylor. With me today

10:02:46 22 is Siegmund Gutman from Proskauer Rose, Catrina Wang, also

10:02:50 23 from Proskauer Rose, Nancy Gettel, xsenior counsel at Amgen.

10:02:55 24 In the first row, I believe Your Honor has met Michelle

10:03:00 25 Ovanesian from Young Conaway.

10:04:51 1 You assert in your papers, Mr. Gutman and his

10:04:53 2 colleagues make an attempt to distinguish the Katz case. I

10:04:58 3 don't know what you would have it distinguished, quite

10:05:00 4 frankly, Mr. Berl.

10:05:03 5 You should listen to me rather than write.

10:05:09 6 We think quite frankly you are on a slippery

10:05:12 7 slope, as is the CAFC for that matter, in its discussion. I

10:05:16 8 am not even sure that it is a matter uniquely in the

10:05:20 9 territory of patent law or patent land. It shouldn't have

10:05:25 10 been, the Katz case, rather, in the Third Circuit or the

10:05:30 11 relevant Circuit Court. In other words, maybe the complaint

10:05:33 12 is better suited to resolution, that Katz added to the

10:05:38 13 regional circuit.

10:05:39 14 But reasonable people can disagree over that.

10:05:42 15 And I understand my colleagues at the CAFC taking an

10:05:46 16 interest in the subject matter, given that patents were

10:05:52 17 involved.

10:05:54 18 The best way to handle, and to, I think,

10:06:00 19 influence a Court's thinking and this particular Judge's

10:06:04 20 thinking, Mr. Berl, is to make a rational, clear and

10:06:09 21 succinct argument as to why you think your schedule should

10:06:13 22 prevail over the defendant's, or for that matter what I

10:06:20 23 perceive to be the identified complaint in your papers with

10:06:23 24 the order that I entered concerning paring down of the 26

10:06:28 25 patents to eight. The four-month difference between your

11:12:01 **1** have all the safe harbor information. We are going to be
 11:12:03 **2** back to square one, as we were with the manufacturing
 11:12:07 **3** information issue.
 11:12:07 **4** All I am saying is that it's fair to focus on
 11:12:12 **5** the manufacturing information before they have to make their
 11:12:16 **6** selection. I think that they have all of the information.
 11:12:20 **7** But as a compromise, right. We are engaged in discovery, we
 11:12:23 **8** are going to have 30(b)(6) depositions. But for them to now
 11:12:27 **9** throw another issue into the pot and say, and, by the way,
 11:12:30 **10** just like manufacturing, we want safe harbor information,
 11:12:34 **11** and then next week they will come up with another issue they
 11:12:38 **12** need, even though it is not our burden, we need your failure
 11:12:42 **13** to mark information and we need this information and that
 11:12:45 **14** information, and that's what I was referring to earlier as
 11:12:48 **15** moving the goalposts.
 11:12:52 **16** So I will end with this, Your Honor. I think
 11:12:56 **17** where we are at is a good place, where we have got the
 11:12:59 **18** deadlines for their choosing certain patents and certain
 11:13:05 **19** claims. We are at a good point with the manufacturing
 11:13:08 **20** information. If they want certain specific information and
 11:13:11 **21** they bring that to light in some reasonable way, we can
 11:13:16 **22** search for it and produce it if we have it. And they can
 11:13:19 **23** certainly take depositions. But to now throw in another
 11:13:23 **24** issue, we will respond to their discovery in due course.
 11:13:28 **25** By the way, even though they purport that they

11:13:29 **1** really need this information to make the selection, it was
 11:13:32 **2** absent for some reason from their first set of document
 11:13:36 **3** requests. If it was that important, why not include it in
 11:13:40 **4** the first set of requests? Why wait six weeks or however
 11:13:45 **5** long it was into the case in order to say, oh, here is more
 11:13:49 **6** information that we need?
 11:13:51 **7** THE COURT: Fair question.
 11:13:53 **8** Mr. Berl, before you stand up, let me ask for
 11:13:57 **9** your reaction and I will get Mr. Gutman to respond, to this
 11:14:00 **10** suggestion, it's just, I am throwing it out there: If it
 11:14:07 **11** should come to pass that the 271 subsection information is
 11:14:17 **12** not in their possession or forthcoming within the time frame
 11:14:21 **13** we set for selection, and information comes into their
 11:14:28 **14** possession that further informs what they would have done
 11:14:33 **15** before the deadline for the patents they would have
 11:14:41 **16** selected, would you be willing to build into the schedule,
 11:14:44 **17** perhaps, an opportunity to add -- I will just pick a
 11:14:51 **18** number -- two patents, at a time that would not blow up the
 11:14:54 **19** schedule, after some discussion with the Court, an
 11:15:03 **20** opportunity to say, No, Judge, these two patents they
 11:15:09 **21** shouldn't be able to add?
 11:15:12 **22** MR. GUTMAN: Your Honor, what you are saying
 11:15:15 **23** makes sense. The problem that I have with it is that there
 11:15:21 **24** is no defined set of information that we can all agree on
 11:15:27 **25** that they need in order to be able to make the assessment.

11:15:31 **1** The concern I have is ten months down the road
 11:15:34 **2** they throw up an issue and say, well, we didn't have any
 11:15:37 **3** discovery on this issue, and had we had that we would we
 11:15:41 **4** would have made a different decision.
 11:15:42 **5** THE COURT: Could you imagine some parameters
 11:15:44 **6** that you could place, the Court could place around the
 11:15:47 **7** information that would be permissible to seek?
 11:15:50 **8** MR. GUTMAN: I would have to think about that,
 11:15:52 **9** Your Honor. There could be a way forward on that. The
 11:15:55 **10** problem is, we are now talking about safe harbor. I don't
 11:16:00 **11** think safe harbor is an appropriate issue that they need in
 11:16:02 **12** order to inform their decision.
 11:16:04 **13** THE COURT: I am trying to do my best to, as
 11:16:10 **14** judges are want to do, to try to figure out a midpoint, if
 11:16:15 **15** there is one, without me arbitrarily lopping off one side or
 11:16:22 **16** the other's hand or whatever, that might accommodate both
 11:16:27 **17** parties' interests.
 11:16:29 **18** I am rather persuaded by your point, your points
 11:16:36 **19** regarding the plaintiff needing to make a selection. But I
 11:16:44 **20** am also persuaded by Mr. Berl's point about this is part of
 11:16:51 **21** a process whether we are going to assert rights that our
 11:16:56 **22** client owns and has a right to vindicate because your client
 11:17:02 **23** has alleged infringing activities and not wanting to
 11:17:12 **24** inappropriately prematurely, as was the argument in Katz,
 11:17:20 **25** and I am sure is the argument in those cases you looked at,

11:17:24 **1** cut off an opportunity, it could be in any kind of case, any
 11:17:28 **2** kind of complex, or non complex case for that matter, in the
 11:17:32 **3** civil arena, not wanting to do that to the plaintiff, being
 11:17:38 **4** sensitive to the case management, the decision-making
 11:17:44 **5** obligations that lawyers have and the calls they have to
 11:17:48 **6** make, being sensitive, as I am, to the contention, if it was
 11:17:57 **7** Mr. Gaffney about the "in the dark" comment, whoever said
 11:18:02 **8** it, resonates as well.
 11:18:03 **9** That is why as I was sitting here listening to
 11:18:06 **10** both of you, wondered whether we could figure out a way to
 11:18:10 **11** address both parties' interests, in getting to the deadline
 11:18:15 **12** on the decision and considering factors that both parties
 11:18:21 **13** feel are appropriate to consider, even though you may not
 11:18:24 **14** agree on them, what factors are appropriate for
 11:18:26 **15** consideration, getting the information exchanged in a manner
 11:18:32 **16** that is timely to enable the decision to be made and also,
 11:18:37 **17** if something happens that either we didn't expect or that
 11:18:43 **18** was unforeseeable, providing a mechanism for the parties to
 11:18:46 **19** raise that issue again with the Court and placing a cap on
 11:18:51 **20** the ability of the plaintiff to support new patents or
 11:18:56 **21** additional patents, a cap that would have very tight
 11:19:00 **22** parameters around it.
 11:19:01 **23** MR. BERL: That would be acceptable, Your Honor.
 11:19:03 **24** And with respect to what Mr. Gutman said about our
 11:19:07 **25** discovery, I disagree with all of it. If you want a

Exhibit B

1

3

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

GENENTECH, INC.,) Civil Action
)
 Plaintiff,)
)
 v.)
)
 AMGEN INC.,) Nos. 17-1407-GMS,
) 17-1471-GMS, and
 Defendant.) 17-1472-GMS

- - -

Wilmington, Delaware
 Thursday, July 26, 2018
 2:00 p.m.
 Telephone Conference

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Senior Judge,
 U.S. District Court,
 District of Delaware

- - -

APPEARANCES:

DANIEL M. SILVER, ESQ., and
 BENJAMIN A. SMYTH, ESQ.
 McCarter & English, LLP
 -and-
 PAUL B. GAFFNEY, ESQ., and
 TEAGAN J. GREGORY, ESQ.
 Williams & Connolly LLP
 (Washington, DC)
 Counsel for Plaintiff

JAMES HIGGINS, ESQ.
 Young Conaway Stargatt & Taylor LLP
 -and-
 SIEGMUND Y. GUTMAN, ESQ.
 Proskauer LLP
 (Los Angeles, CA)
 Counsel for Defendant

14:08:50 1 guys were going to pare it down. Right? You were going
 14:08:52 2 work on that?
 14:08:53 3 MR. GUTMAN: That's right, Your Honor.
 14:08:55 4 So Your Honor issued an order during the July
 14:09:00 5 11th hearing to have it pared down to 50 topics. There was
 14:09:06 6 a discussion about plaintiffs selecting 50 topics from their
 14:09:13 7 original 236 topics to pare down, and that Amgen will
 14:09:18 8 possibly, then, provide written responses to those topics.
 14:09:27 9 Shortly after the hearing, plaintiffs served on
 14:09:32 10 Amgen an entirely new list that had 49 topics, but they
 14:09:41 11 didn't narrow down the original 30(b)(6) notice at all.
 14:09:46 12 What they ended up doing was taking multiple topics from the
 14:09:50 13 original notice that had the 236 topics and essentially just
 14:09:56 14 consolidating them and separating them by commas in their 49
 14:10:02 15 topics, and reserved the right to continue with Amgen's
 14:10:08 16 30(b)(6) deposition on any originally served topics that
 14:10:13 17 were not part of their re-served 30(b)(6) list.
 14:10:18 18 Then they even went so far as to actually
 14:10:22 19 include new subject matter in their re-served notice that
 14:10:27 20 wasn't anywhere in their original notice.
 14:10:31 21 Unfortunately, they didn't narrow the scope of
 14:10:34 22 the original notice at all.
 14:10:37 23 So we are getting to the point where, as we
 14:10:42 24 discussed at the July 11th hearing, they could have served
 14:10:47 25 the original notice on us much earlier than they did, which

2

4

14:07:37 1 THE COURT: All right, counsel. Who is on the
 14:07:39 2 line for the plaintiff, please?
 14:07:43 3 MR. SILVER: Good afternoon, Your Honor. Dan
 14:07:47 4 Silver from McCarter & English, and also my colleague Ben
 14:07:48 5 Smyth from the Wilmington office. Also, Paul Gaffney and
 14:07:52 6 Teagan Gregory are on as well.
 14:07:54 7 THE COURT: Who is going to handle the call for
 14:07:56 8 Genentech?
 14:07:57 9 MR. SILVER: It will be Mr. Gaffney, Your Honor.
 14:08:00 10 THE COURT: Okay.
 14:08:01 11 For Amgen.
 14:08:02 12 MR. HIGGINS: Good afternoon, Your Honor. Jim
 14:08:05 13 Higgins from Young Conaway. With me is Siegmund Gutman from
 14:08:12 14 Proskauer.
 14:08:12 15 THE COURT: Good morning, Mr. Gutman.
 14:08:16 16 MR. GUTMAN: Good morning, Your Honor.
 14:08:16 17 This is, I think, your complaint, Mr. Gutman.
 14:08:22 18 Is that correct?
 14:08:22 19 MR. GUTMAN: Yes, it is, Your Honor.
 14:08:26 20 THE COURT: Go ahead.
 14:08:27 21 MR. GUTMAN: So, Your Honor, as you might recall
 14:08:33 22 from the July 11th hearing, there was an issue with respect
 14:08:37 23 to an original 30(b)(6) notice that plaintiffs served on
 14:08:43 24 Amgen that included 236 topics.
 14:08:47 25 THE COURT: We were going to pare it down, you

14:10:52 1 was right before the July 4th holiday. They haven't
 14:10:56 2 complied with Your Honor's order from the July 11th hearing.
 14:11:01 3 And, frankly, we are running out of time and we are running
 14:11:04 4 we are running out of resources here that would allow Amgen
 14:11:10 5 adequate time to educate a witness on the 50 topics they
 14:11:15 6 were supposed to select and then have the deposition before
 14:11:20 7 the August 31st deadline by which plaintiff needs to select
 14:11:25 8 the eight patents.
 14:11:26 9 So we are back before Your Honor. We tried to
 14:11:29 10 work this out with them during the meet-and-confer. And
 14:11:33 11 what we were told during the meet-and-confer was, their
 14:11:37 12 re-served notice, which was actually broader than their
 14:11:40 13 original notice, was operative and that they were going to
 14:11:45 14 force us to produce witnesses to testify on those topics
 14:11:50 15 even though the notice didn't comply with the discussion
 14:11:53 16 that we had during the July 11 hearing.
 14:11:56 17 And they told us that if we wanted relief we had
 14:11:59 18 to go to the Court and seek a protective order.
 14:12:02 19 So plaintiffs -- we are reluctantly before Your
 14:12:06 20 Honor, but unfortunately, plaintiffs left us with no other
 14:12:11 21 option than to seek relief and try to figure it out.
 14:12:15 22 So that's why we are here, Your Honor.
 14:12:17 23 THE COURT: Okay. Can you hold just a second
 14:12:19 24 before we get a response.
 14:12:22 25 (Pause.)

14:19:38 **1** topics, and there were numerous topics that had questions on

14:19:41 **2** a single issue related to a single patent. And we took that

14:19:45 **3** up to a higher level of generality, for sure.

14:19:49 **4** So, for example, one question, one topic we

14:19:57 **5** listed on our first notice was -- had literally this level

14:20:03 **6** of specificity: the conductivity of the buffer solution

14:20:07 **7** used at the (inaudible) in the cation exchange

14:20:12 **8** chromatography process.

14:20:17 **9** There were a number of topics on the cation

14:20:21 **10** exchange process buffer. So we modified the topic to be:

14:20:27 **11** the buffer solution used in the cation exchange

14:20:30 **12** chromatography process used in the manufacture of their

14:20:33 **13** product, including the composition of the buffer, the salt

14:20:38 **14** concentrations, et cetera.

14:20:39 **15** All perfectly appropriate Rule 30(b)(6) topics,

14:20:45 **16** in less detail, and probably makes it a little harder,

14:20:50 **17** actually, than our first notice in preparing a witness

14:20:52 **18** because we are not identifying exactly what we want.

14:20:57 **19** But we are forced to take it to a higher level

14:21:03 **20** of generality.

14:21:04 **21** Again, the unfairness is that we were asking

14:21:07 **22** very specifically back in May before we served the notice

23 what they asked for.

14:21:21 **24** You know, as I said, Your Honor, we need, we,

14:21:26 **25** Genentech, we have been ordered to drop most of our

14:21:29 **1** patents --

14:21:31 **2** THE COURT: I don't know that that is exactly a

14:21:34 **3** fair characterization -- but go ahead -- that you have been

14:21:37 **4** ordered to drop certain patents.

14:21:40 **5** MR. GAFFNEY: The scheduling order tells us to

14:21:42 **6** reduce the number of patents.

14:21:44 **7** THE COURT: Right. That scheduling order has

14:21:45 **8** resulted from very extensive conversations. I don't want

14:21:51 **9** any reviewing Court to read that and say, well, the Judge

14:21:56 **10** acted arbitrarily, or you to be able to argue that I acted

14:22:01 **11** arbitrarily.

14:22:01 **12** Do you understand my point?

14:22:03 **13** MR. GAFFNEY: Absolutely, Your Honor. I don't

14:22:06 **14** mean -- what I do mean to say is -- I am sorry, I didn't

14:22:11 **15** mean to cut you off.

14:22:12 **16** THE COURT: Go ahead.

14:22:15 **17** MR. GAFFNEY: What I did mean to say is that we

14:22:18 **18** did not want to reduce the patents to eight on the schedule

14:22:21 **19** that we were given, but we are going to do that. It was

14:22:28 **20** certainly the case and I think we were all clear that we

14:22:32 **21** were entitled to adequate discovery to make an intelligent

14:22:36 **22** decision of which ones to drop.

14:22:38 **23** THE COURT: No doubt about that. That is not

14:22:40 **24** something of which you have to convince me. That makes

14:22:42 **25** sense I hope to everyone on the line.

14:22:47 **1** MR. GAFFNEY: Thank you, Your Honor. What I

14:22:49 **2** would say is that the notice that they are complaining about

14:22:58 **3** today, it would not surprise you, with the letter -- that is

14:23:05 **4** Docket Item No. 133. I submit, Your Honor, in return that

14:23:14 **5** it is utterly important and appropriate in a case of this

14:23:16 **6** magnitude. We need discovery on that.

14:23:21 **7** THE COURT: Okay.

14:23:23 **8** MR. GAFFNEY: Again, I am surprised we haven't

14:23:26 **9** started already because we have asked for the date, we have

14:23:29 **10** asked for a witness. Not every topic is objectionable. So

14:23:33 **11** what we should be dealing with here is that we should get a

14:23:39 **12** date -- we have offered to take the deposition in Los

14:23:41 **13** Angeles. We have offered to negotiate on a date. But let's

14:23:45 **14** get started. If there are topics on the new notice that are

14:23:49 **15** objectionable, let's meet and confer on those, and if

14:23:53 **16** necessary -- and I hope it's not -- bring it to Your Honor.

14:23:57 **17** But the way to keep the schedule is not to come

14:24:01 **18** back and say, I want you to pick 50 topics from your notice.

14:24:12 **19** That's not fair to us. They got a notice. We should get

14:24:17 **20** going.

14:24:18 **21** THE COURT: Okay. Before I open the floor up

14:24:23 **22** again, is there anything else you want to say?

14:24:25 **23** I will give you adequate time to respond.

14:24:29 **24** MR. GAFFNEY: Your Honor, if I may, Mr. Gregory,

14:24:32 **25** as I mentioned, was on the meet-and-confer. Mr. McCloud is

14:24:38 **1** on vacation this week. I understand from him, but I wanted

14:24:41 **2** to confirm that, that we asked repeatedly what information,

14:24:47 **3** what new subjects should be added to the notice. I will let

14:24:53 **4** Mr. Gregory address that.

14:24:55 **5** THE COURT: Mr. Gregory.

14:24:56 **6** MR. GREGORY: Yes, Your Honor. Teagan Gregory

14:24:58 **7** for Genentech.

14:24:59 **8** I did sit in on the telephonic meet-and-confer

14:25:03 **9** that we had last Friday. We asked by my count at least six

14:25:08 **10** or seven times for Amgen to identify for us what new matter,

14:25:14 **11** specifically was the alleged new matter to the revised

14:25:18 **12** notice, given the original notice that was served back in

14:25:21 **13** June.

14:25:22 **14** He complains during that meet-and-confer call,

14:25:28 **15** on all six or seven of those, Amgen refused to identify the

14:25:34 **16** alleged new subject matter that had been added to the

14:25:38 **17** revised notice of the 30(b)(6).

14:25:40 **18** THE COURT: Anything else from plaintiff's

14:25:43 **19** perspective before I get back to Mr. Gutman?

14:25:47 **20** MR. GAFFNEY: No, Your Honor. Thank you.

14:25:49 **21** THE COURT: Mr. Gutman, I am not going to allow

14:25:54 **22** the parties to take me all around Robin Hood's barn again as

14:25:59 **23** I have in the past. We are coming to the short end of my

14:26:02 **24** rope.

14:26:04 **25** What is the matter with Mr. Gaffney's suggestion

Exhibit C

**THIS DOCUMENT HAS
BEEN REDACTED IN ITS
ENTIRETY**

CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that true and correct copies of the foregoing document were caused to be served on October 9, 2018 on the following counsel in the manner indicated:

VIA EMAIL:

Melanie K. Sharp
James L. Higgins
YOUNG CONAWAY STARGATT & TAYLOR LLP
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
msharp@ycst.com
jhiggins@ycst.com

OF COUNSEL:

Siegmund Gutman
PROSKAUER ROSE LLP
2049 Century Park East, Suite 3200
Los Angeles, CA 90067-3206
(310) 284-4533
Fax: (310) 557-2193
sgutman@proskauer.com

Steven M. Bauer
PROSKAUER ROSE LLP
One International Place
Boston, MA 02110
(617) 526-9600
sbauer@proskauer.com

Attorneys for Defendant

Dated: October 9, 2018

/s/ Daniel M. Silver
Daniel M. Silver (#4758)